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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

7590 04/15/2004

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No. 09/269,845	Applicant(s) JANUSZ ET AL.	
	Examiner <i>Roy Teller</i> Christopher R. Tate	Art Unit 1654	

All participants (applicant, applicant's representative, PTO personnel):

(1) Christopher R. Tate.

(3) Randy Digges.

(2) Roy Teller.

(4) Marian Kruzel.

Date of Interview: 13 April 2004.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: All, in general.

Identification of prior art discussed: All, in general.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Based upon Applicants arguments and evidence presented during the interview including journal articles (as well as the teachings within the instant specification) concerning the effective use of colostrinin in treating dementia/Alzheimer's disease, it was agreed upon that the USC 112, first paragraph rejection of record would be withdrawn. The Examiners informed Applicants' representatives that various prior art references (i.e., prior to 1996) of record (including those cited in the International Search Report) disclosing colostrinin compositions would be used as USC 102 and/or 103 rejections against the instant product claims. However, Examiners stated that they felt the instant method claims would be allowable, provided no additional prior art is found concerning such methods of use.

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FACSIMILE TO	Mr. Roy R. Teller, Art Unit 1654
	U.S. Patent and Trademark Office
FACSMILE TEL. NO.	571-273-0971
FROM	Randolph E. Digges, III
DATE	6 April 2004
CLEVELAND TIME	16:07
NUMBER OF PAGES (INCLUDING THIS PAGE)	61
RE	U.S. Patent Application No. 09/269,845 Filed September 24, 1999 For "Colostrinin and Uses Thereof"
OUR REF.	AAT-11612

Applicant Initiated Interview Request Form

Application No.: 09 / 269,845 First Named Applicant: Maria Janusz et al.
Examiner: Roy R. Teller Art Unit: 1654 Status of Application: Pending

Tentative Participants:

(1) Randolph E. Digges, III (2) Dr. Marian L. Kruzel
(3) _____ (4) _____

Proposed Date of Interview: 13 April 2004 Proposed Time: 10:00 AM (AM/PM)

Type of Interview Requested:

(1) ☐ Telephonic (2) ☒ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☒ NO

If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>REJ. §112</u>	<u>15, 16, 24, 26-32, 35, 54 and 58-68</u>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) <u>REJ. §102</u>	<u>40, 41 and 54</u>	<u>Burrin et al.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) <u>REJ. §103</u>	<u>40, 41 and 54</u>	<u>Burrin et al.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☒ Continuation Sheet Attached

Brief Description of Arguments to be Presented:

Summary of issues to be discussed and copies of documents supporting applicants' positions thereon are
attached hereto.

An interview was conducted on the above-identified application on _____.

NOTE:

This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

(Applicant/Applicant's Representative Signature)

(Examiner/SPE Signature)

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Applicants' counsel of record and Dr. Marian L. Kruzel intend to discuss the following issues, claims and supporting materials during the April 13, 2004 Interview:

I. Rejection of Claims 15, 16, 24, 26-32, 35, 40, 41, 54 and 58-68 Under 35 U.S.C. §112

Dr. Kruzel will discuss three articles that report the findings of clinical studies pertaining to the use of Colostrinin for the treatment of Alzheimer's Disease and dementia in human patents:

1. *Colostrinin®: a Proline-Rich Polypeptide (PRP) Complex Isolated from Ovine Colostrum for Treatment of Alzheimer's Disease. A Double-Blind, Placebo-Controlled Study*, Jerzy Leszek et al., *Archivum Immunologiae et Therapiae Experimentalis*, 1999, 47, 377-385 (see copy attached hereto as Article 1).
2. *Colostrinin® proline-rich polypeptide complex from ovine colostrum - a long term study of its efficacy in Alzheimer's disease*, Jerzy Leszek et al., http://www.MedSciMonit.com/pub/vol_8/no_10/2362.pdf, (2002) (see copy attached hereto as Article 2).
3. *Colostrinin (a naturally occurring, proline-rich, polypeptide mixture) in the treatment of Alzheimer's disease*, *Journal of Alzheimer's Disease* 6 (2004) 17-26 (see copy attached hereto as Article 3).

Dr. Kruzel will compare the treatment protocols followed in such studies with the treatment protocol taught in the present application.

In addition, Dr. Kruzel will discuss the Examiner's characterization of the findings of his article:

4. *Towards an Understanding of Biological Role of Colostrinin Peptides*, *Journal of Molecular Neuroscience*, 2001, vol. 17, pp 379-389 (see copy attached hereto as Article 4).

In response to the Examiner's contention that Alzheimer's Disease can only be diagnosed post-mortem with the dissection of the brain, Dr. Kruzel will discuss various tests that are used to diagnose Alzheimer's Disease in living human patients to a 90% accuracy rate.

Applicants' counsel of record will direct the Examiner's attention to several granted U.S. Patents that include claims directed to the treatment of Alzheimer's Disease: Golec et al., U.S. Pat. No. 6,632,962 (claim 5); Uchida et al., U.S. Pat. No. 6,624,162 (claim 9); Balandrin et al., U.S. Pat. No. 6,617,358 (claim 12); and Lee et al., U.S. Pat. No. 6,469,055 (claims 2 and 3). Applicants' counsel will also direct the Examiner's attention to patents granted in other countries from the corresponding application.

Dr. Kruzel will discuss two articles that report the findings of investigative studies wherein the nonapeptide disclosed in the present application was shown to provide beneficial cognitive effects on animals:

5. *Colostrinin, a Polypeptide Isolated From Early Milk, Facilitates Learning and Memory in Rats*, Piotr Popik et al., *Pharmacology Biochemistry and Behavior*, Vol. 64, No. 1, pp. 183-189 (1999) (see copy attached hereto as Article 5).
6. *Colostrinin® proline-rich polypeptide complex from ovine colostrum - a long term study of its efficacy in Alzheimer's disease*, Jerzy Leszek et al., http://www.MedSciMonit.com/pub/vol_8/no_10/2362.pdf, (2002) (see copy attached hereto as Article 6).

II. Rejection of Claims 40, 41, 54 Under 35 U.S.C. §102(b)

Dr. Kruzel will discuss the differences between the invention claimed in claims 40, 41 and 54 and the information disclosed in the Burrin et al. article cited by the Examiner, namely:

7. *Nutrient-Independent and Nutrient-Dependent Factors Stimulate Protein Synthesis in Colostrum-Fed Newborn Pigs*, Douglas G. Burrin et al., Pediatric Research, Vol. 37, No. 5, pp. 593-599 (1995) (see copy attached hereto as Article 7).

Furthermore, Dr. Kruzel will direct the Examiner's attention to Nichols et al., U.S. Pat. No. 4,977,137, which discloses that milk lactoferrin promotes growth of gastrointestinal tract of human infants and newborn nonhuman animals. Dr. Kruzel will explain why the Burrin et al. article cited by the Examiner does not anticipate the claims of the present application.

III. Rejection of Claims 40, 41, 54 Under 35 U.S.C. §103(a)

Dr. Kruzel will explain why one of ordinary skill in the art would not find applicants' claimed invention obvious in view of the Burrin et al. article.